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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,919	05/10/2001	Qingsheng Zhu	279.330US1	4736

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ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/852,919	ZHU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 10 May 2001.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8, 10-14 and 16-20 is/are rejected.

7) Claim(s) 9 and 15 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 10 May 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Claim Rejections - 35 USC § 101*

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13, 14 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the following phrases amount to inferential recitation of the body, which renders these claim non-statutory:

- “positioned in a vein” (claim 13),
- “the electrodes spaced... in a body” (claim 14), and
- “leads positioned in an anterior vein and a second of the two leads is position in a lateral vein” (claim 15).

A phrase such as:

- “adapted to be positioned in a vein” (claim 13),
- “the electrodes adapted to be spaced... in a body” (claim 14), and
- “leads adapted to be positioned in an anterior vein and a second of the two leads adapted to be positioned in a lateral vein” (claim 15).

is suggested to address the understood intent of the applicant and avoid the 35 U.S.C. 101 rejection. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, "the refractory period" and "the non-refractory period" lack antecedent basis.

Claim 20 is unclear because in line 2 it appears "hear" should be --heart--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 10, 16, 18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by KenKnight et al. (US 6317615). Ken Knight et al. disclose an apparatus to prevent plaque build-up (c 1, ll 31-45) in a coronary artery (c 13, ll 5-8). The pulse generator (140) includes an electrogram analysis circuit (222). A non-excitatory electrical field is generated after the heart depolarization at a level less than needed to capture the tissue (c 2, ll 54-58 and c 4, ll 47-60).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) in view of Dev et al. (US 6347247).

Chekanov discloses a method of prevention and treatment of atherosclerosis in blood vessels. The implantable generator (25) (c 2, ll 25-34) is connected one or two leads (c 3, ll 42-49) and an electrical field is created to prevent plaque build-up. Chekanov discloses the claimed invention except for:

- applying the method to the coronary artery (claim 1),
- the lead including an electrode patch (claim 2),
- inserting the lead into a vein adjacent to the coronary artery (claim 3),
- spacing the electrical fields about 10 seconds apart (claim 6), and
- the lead having two electrodes (claim 7).

Dev et al. disclose a device to dilate vessels using electrical fields to prevent plaque build-up (c 2, ll 47-51 and c 6, ll 21-27) and teach that it is known to apply the method to the coronary artery, use an electrode patch or adjacent vein to establish the electrical field, space the

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electrical fields about 10 seconds apart and provide two electrodes. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of prevention and treatment of atherosclerosis in a blood vessel as taught by Chekanov, with the following elements as taught by Dev et al.:

- applying the method to the coronary artery (claim 1) (c 17, ll 64-67) to provide treatment for a commonly occluded vessel,
- the lead including an electrode patch (claim 2) (figure 3, Pure Silver Plate, given that the electrodes can be external or internal, hence an epicardial patch (c 6, ll 28-35)) to provide an electrode that enable creation of a broad electrical field enabling treatments of large areas of cardiac tissue,
- inserting the lead into a vein adjacent to the coronary artery (claim 3) (c 6, ll 28-35 given the vessel is an exo-luminal site relative to the vessel being treated) to provide a secure location for an electrode that enables creation of the electrical field,
- spacing the electrical fields about 10 seconds apart (claim 6) (c 7, ll 45-46) where one second or longer is read as about 10 seconds) to have a pulse timing sequence that is effective in treating plaque build-up, and
- the lead having two electrodes (claim 7) (c 10, ll 26-30) to enable versatility in the creation of the electrical field.

6. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) in view of Dev et al. (US 6347247) and further in view of KenKnight

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(US 6317615) as related to claim 1. As discussed in paragraph 4 of this action, modified Chekanov discloses the claimed invention except for sensing a heart rhythm and generating a non-excitatory electrical field after the heart depolarization.

Ken Knight et al. disclose an apparatus to prevent plaque build-up (c 1, ll 31-45) in a coronary artery (c 13, ll 5-8). The pulse generator (140) includes an electrogram analysis circuit (222). KenKnight et al. teach that it is known to sense a heart rhythm and generate a non-excitatory electrical field after the heart depolarization (c 2, ll 54-58). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method of prevention and treatment of atherosclerosis in a blood vessel as taught by modified Chekanov, with the sensing of the heart rhythm and generating a non-excitatory electrical field after the heart depolarization as taught by KenKnight et al. to ensure the electrical pulses and resulting electrical fields do not adversely impact the cardiac cycle.

7. Claims 11, 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight et al. (US 6317615) in view of Chekanov (US 6201991). As discussed in paragraph 2 of this action, KenKnight et al. discloses the claimed invention except for:

- the generating device being implantable (claim 11),
- the system having two leads (claim 14) and
- the generating device including therapy circuits (claim 19).

Chekanov discloses a method of prevention and treatment of atherosclerosis in blood vessels and teaches the use of an implantable generator (25) that includes therapy circuits and a system that includes one or two leads to create an electrical field to prevent plaque build-up. Therefore it would have been obvious to one having ordinary skill in the art at the time the

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invention was made to modify the apparatus to prevent plaque build-up as taught by KenKnight et al., with the following elements as taught by Chekanov:

- the generating device being implantable (claim 11) (c 2, ll 25-34) to enable patient mobility and enable a convenient means for frequent treatments,
- the system having two leads (claim 14) (c 3, ll 42-49) to allow diverse electrical fields to be created based on the patient's needs, and
- the generating device including therapy circuits (claim 19) (c 2, ll 25-34) to conveniently provide the patient with a single device to address cardiac stimulation therapy needs and to provide the ongoing electrical field treatment for atherosclerosis.

8. Claims 12, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight et al. (US 6317615) in view of Dev et al. (US 6347247). As discussed in paragraph 3 of this action, KenKnight et al. disclose the claimed invention except for:

- the lead including an electrode patch (claim 12),
- inserting the lead into a vein adjacent to the coronary artery (claim 13), and
- spacing the electrical fields less than every 10 seconds apart (claim 17).

Dev et al. disclose a device to dilate vessels using electrical fields to prevent plaque build-up (c 2, ll 47-51 and c 6, ll 21-27) and teach that it is known to use an electrode patch or adjacent vein to establish the electrical field and to space the electrical fields less than every 10 seconds apart. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus to prevent plaque build-up as taught by KenKnight et al., with the following elements as taught by Dev et al.:

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- the lead including an electrode patch (claim 12) (figure 3, Pure Silver Plate, given that the electrodes can be external or internal, hence an epicardial patch (c 6, ll 28-35)) to provide an electrode that enable creation of a broad electrical field enabling treatments of large areas of cardiac tissue,
- inserting the lead into a vein adjacent to the coronary artery (claim 13) (c 6, ll 28-35 given the vessel is an exo-luminal site relative to the vessel being treated) to provide a secure location for an electrode that enables creation of the electrical field, and
- spacing the electrical fields about 10 seconds apart (claim 17) (c 7, ll 45-46) where one second or longer is read as about 10 seconds) to have a pulse timing sequence that is effective in treating plaque build-up.

***Allowable Subject Matter***

9. Claim 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. Claim 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the rejection under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

10/25/02

Angela D. Sykes

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